UNITED STATES DEPARTMENT OF COMMERCE
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ID

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/276,868	03/26/99	SIMONS	M BIS-043

EXAMINER

HM22/0221

DAVID PRASHKER PC
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ART UNIT	PAPER NUMBER
1653	12

MOEZIE,F

DATE MAILED: 02/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/276,868	Simoms
Examiner	**Group Art Unit**
F. T. Moezie	1653

☒ Responsive to communication(s) filed on *Aug 24, 2000* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-15* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-15* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *11*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

STATUS OF CLAIMS

Claims 1-15 are pending prosecution in this Office action.

Claims 1-2, 5-6, and 11-14 have been amended once and claim 15 has been newly added.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

OBJECTION - SPECIFICATION

The specification remains objectionable regarding Fig 10. Fig 10 "presents table 4", a) the SEQ ID NO is

numbered as SEQ ID NO 6 (amendment filed, July 26, 1999) and b) the cited SEQ ID NO is incorrect (compare this sequence with the SEQ ID NO 1 at page 23 of the specification). Applicant is advised to review and correct, if necessary, ALL of the SEQ ID NOS entered into the specification.

Furthermore, the instructions given for the entry of SEQ ID NOS "In the Drawings" (7/26/99) have not been entered. Said entries belong to the text section of the specification entitled BRIEF DESCRIPTION OF THE FIGURES at page 7 of the specification.

The compliance with the Requirements for Patent Applications containg Amino Acid Sequence Disclosures is incomplete.

NOTE: Upon compliance with the requirements applicant must also amend the application to provide the SEQ ID NOS inTHE SPECIFICATION (at least in the first occurance), in ALL EXAMPLES, TABLES and THE CLAIMS.

NEW GROUNDS OF REJECTION

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terminology "functionally" broadens the scope of the claims beyond the term "selectively" insofar as "functionally" includes "selectively" and more. Hence, it introduces New Matter into the claims. The substitution of term "discriminating" for "selective" introduces New Matter for much the same reasons just cited. The substitution of the term "functionally" for "markedly" introduces New Matter into the claims. The introduction of the term "functionally" is a question of change in the substance of the claims, whereas "markedly" is a question of change in degree. Finally, applicant has not pointed out the basis for the above substitutions in the specification as filed. See MPEP Sections 2163.06 and 714.02.

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In claim 5 the terminology "receptor-specific peptide mean, and slow-releasing means for peptide secretion in living cells and sequestered organisms" lack description in the specification as filed.

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In claim 6, the use of DNA sequence coding for expression of peptides are not described in the specification. According to the recent article in The Washington Post even the well recognized "gene therapy" in treating diabetes is still in the experimental stages. Clearly, the so called 'conventionally recognized today as "gene therapy" modes of delivery' is still in its/their infancy as evidence by the lack of citations in the specification.

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Claim 2, and claims dependent thereon are rejected under 35 USC 112, first paragraph, regarding the utility for the methods as claimed. The utility, "a method for discriminating inhibition of proteasome-mediated degradation of peptides in-situ within a collection of viable cells---" is not considered credible and /or substantial.

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Claims 11 and 15 are rejected under 35 U.S.C. 102 (a)/103(a) as being unpatentable over Blecha et al., US Patent No. 5,830,993, filing date 10 April 1955.

The patent '993 discloses a family of PR-39: "truncated peptides are disclosed which are based upon a known peptide, PR-39 --- The most preferred peptide compound is PR-26" (abstract) wherein the document teaches that PR-26 exhibits a greater activity than PR-39, col. 6, lines 56-57 (PR-26 contains the N-terminal portion of the peptide). Additionally, in Fig. 1, PR-14 and PR-19 which are the N-terminal portions of the peptide PR-39 are taught. See the entire document.

The claims being drawn to a family of N-truncated PR-39 derived oligopeptides whose members are biologically active, are anticipated or rendered obvious over the art. The characteristics and/or properties cited in the instant claims are inherent in the structures of the peptides.

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Claims 1-15 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "functionally" render the claims indefinite as to the claims metes and bounds. The claims are indefinite as to which function is intended in the claims since PR-39 is a multi functional peptide.

The term "discriminating" render the claims indefinite as to in what respect the claimed discriminating occurs.

The terminology "substantially" and "at least partially homologous with the N-terminal amino acid" render the claims indefinite as to the claims metes and bounds. What is considered "at least substantial", "partially homologous" and how many amino acids constitute the "N-terminal amino acid sequence" of native PR-39?

In claim 15, the terminology "alter the functional proteolytic activity of said proteasomes having an interacting ∇7 subunit **such that** a markedly increased expression of at least one specific

peptide occurs" render the claim indefinite as to how or in what way the altering occurs and what is considered markedly?

Claims 1-15 are rejected under 35 USC 112, second paragraph, as being indefinite regarding the required steps in the methods claimed. It is not clear as to how the required steps are monitored and/or the results sought in each step.

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Claims 1-10 remain rejected under 35 USC 102 (b)/103 (a) over the patent to Gallo et al., '273 for the reasons of record, paper no. 8, mailed 3/30/00.

RESPONSE TO AMENDMENTS AND REMARKS

Applicant's arguments filed 24 August 2000, paper no. 10, have been considered and found persuasive in-part.

The earlier objection to the specification is maintained to a limited extent, for the reasons cited above.

The earlier rejection of claims 10-14, regarding the lack of utility is withdrawn in view of the applicants' remarks.

The earlier rejection of the claims 1-10 under 35 USC 112, first paragraph, regarding the paragraph bridging pages 2 and 3 of the Office action mailed 3/30/00, is maintained for the reasons of record. Additionally, for the reasons cited above, this ground of rejection is extended to encompass claim 11 (amended) and the newly added claim 15.

The earlier rejection of the claims under 35 USC 112, second paragraph, is withdrawn in view of the cancellation of the rejected terms. However, this ground of rejection is maintained with respect to the above cited grounds of rejection.

Remarks regarding The Invention as claimed (pages 10+ of Response) has been considered, but not well taken..

The instant application clearly defines the invention: "is particularly directed to mechanisms regulated by PR-39 peptides" (e.g., specification, page 2, lines 16-17).

The claims according to the applicant "explicitly requires that the introduced PR-39 oligopeptide collective member interact with such proteosomes as are present within the cytoplasm of the targeted cell **such that** at least three specifically stated events must occur. ---" has been considered. Clearly, if the peptide of the prior art would bring about the results, i.e., "stimulation of angiogenesis" it inherently follows the specified and postulated mechanism steps. The examiner is not in a position to ascertain the differences, if any. The burden is on the applicant to show the differences. The various events defined in the claims have not shown to be monitored. Finally, the "detailed description of proteasomes, their activity ---" (page 17 of remarks) have been considered, but not found persuasive. Because proteasomes are an integral part of the cytoplasm and are expected to inherently perform their function, as explained by the applicant.

Remarks regarding the rejection of claims 1-10 under 35 USC 102 (b)/103 (a) over Gallo et al., are not convincing. The reference teaches that: a) PR-39 is known in the art and b)

PR-39 is useful in treating angiogenesis (abstract). To be effective in treating angiogenesis it must inherently follow a mechanism for its action. Therefore, the rejection as applied is proper and maintained.

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Any inquiry concerning this communication should be directed to F.T. Moezie at telephone number (703) 305-4508 or Mr. LOW (SPE) at 308-2923.

F.T. Moezie

F. T. MOEZIE, Ph.D.
PRIMARY EXAMINER
ART UNIT 186

The earlier rejection of the claims under 35 USC 112, second paragraph, is withdrawn in view of the cancellation of the rejected terms. However, this ground of rejection is maintained with respect to the above cited grounds of rejection.

Remarks regarding The Invention as claimed (pages 10+ of Response) has been considered, but not well taken..

The instant application clearly defines the invention: "is particularly directed to mechanisms regulated by PR-39 peptides" (e.g., specification, page 2, lines 16-17).

The claims according to the applicant "explicitly requires that the introduced PR-39 oligopeptide collective member interact with such proteasomes as are present within the cytoplasm of the targeted cell **such that** at least three specifically stated events must occur. ---" has been considered. Clearly, if the peptide of the prior art would bring about the results, i.e., "stimulation of angiogenesis" it inherently follows the specified and postulated mechanism steps. Even assuming arguendo that the prior art failed to disclose or suggest a "latent" or "inherent" property, the case law recognizes time and again that "mere recognition of latent properties in the prior art does not render non-obvious an otherwise known invention". See In re Wiseman, 596 F.2d. 1019, 201 USPQ 658 (CCPA 1979). For granting a patent on the discovery of an unknown but inherent function "would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. See 201 USPQ at 661; In re Baxter, 952 F.2d 388, 21 USPQ2d 1281 (Fed. Cir. 1991).

The prior art procedure inherently must follow the stated mechanism because the same protein is applied in the same way in the same amount. *In re Best*, 195 USPQ 430,433 (CCPA 1977); *Ex parte Novitski*, 26 USPQ2d 1389 (B.P.A.I, 1993).

MPEP 2131.01(d) permits the citation of references or evidence in an anticipation rejection under 35 U.S.C. 102 in order to show that a characteristic not disclosed in the reference is inherent.

Finally, the "detailed description of proteasomes, their activity ---" (page 17 of remarks) have been considered, but not found persuasive.. Because proteasomes are an integral part of the cytoplasm and are expected to inherently perform their function, as explained by the applicant.

Remarks regarding the rejection of claims 1-10 under 35 USC 102 (b)/103 (a) over Gallo et al., are not convincing. The reference teaches that: a) PR-39 is known in the art and b) PR-39 is useful in treating angiogenesis (abstract). To be effective in treating angiogenesis it must inherently follow a mechanism for its action. See, the entire document. Therefore, the rejection as applied is proper and maintained.

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Any inquiry concerning this communication should be directed to F.T. Moezie at telephone number (703) 305-4508 or Mr. LOW (SPE) at 308-2923.

. i. MOEZIE, Ph.
PRIMARY EXAMIN
ART UNIT 18